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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/981,559	04/13/1998	DAVID WALLACH	WALLACH=20	8216

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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/981,559	WALLACH ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this c mmunication appears on th cover sh t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's incorporation of arguments in a appeal brief previously filed March 12, 2002 in the transmittal letter accompanying the RCE is acknowledged.

Claims 29 and 36 are pending and being examined.

Maintained Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC §§ 101 and 112

Claims 29, 36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to or encompasses a method of screening for compounds that bind the intracellular domain of 26 kDa TNF and/or modulate the phosphorylation thereof. The specification teaches phosphorylation of the serine residues of the intracellular domain of 26 kDa TNF. However, the biological significance of this phosphorylation is unknown. In the absence of a knowledge of the biological significance of the phosphorylation process there is no apparent specific and substantial

asserted utility or a well established utility for either the screening process or production of the compounds identified by the screening process. Further experimentation is necessary to attribute a utility to the claimed screening process. Evidence warranting further study is not equivalent to evidence showing the type of utility required by 35 U.S.C. 101. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966) (noting that in context of the utility requirement "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

Claims 29, 36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant argues that it is incorrect that the biological significance of this phosphorylation is unknown, citing page 6, lines 3-10, of the specification. Applicants' arguments have been fully considered but they are not persuasive. The specification discloses at page 6, lines 3-10, that the "findings and their related functional significance represent the first disclosure of a control possibility." The specification at the paragraph bridging pages 5-6 also discloses that the sequence conservation of the intracellular domain of TNF indicates that this domain and its phosphorylation play important roles in TNF function. One possibility is that this domain take part in the regulation of proteolytic processing. Another possibility is that this domain may affect TNF function as a ligand. Yet another possibility is that this intracellular domain interacts with other

intracellular molecules. The specification at page 6, full paragraph 1, discloses that the phosphorylation of the intracellular domain of TNF may be involved in the regulation of expression or proteolytic processing of cell-surface TNF, in the modulation of TNF bioactivity, or in the intracellular processes mediated by the cell surface TNF molecules. None of these are specific because the specification does not indicate the specific way in which TNF processing, activity, or interaction are modulated by phosphorylation. Further, the biological significance of the phosphorylation of the intracellular domain of TNF is unknown. Thus the asserted utility in screening for factors that modulate the phosphorylation of the intracellular domain of TNF is not substantial, because further research would have to be conducted to determine which, if any, of TNF activity or processing are modulated and how they are modulated. The specification lacks specific and substantial disclosure of a specific and substantial functional consequence of this phosphorylation. In the absence of a particular disclosed relationship between the phosphorylation of the intracellular domain of TNF and a particular functional consequence, any information obtained from the claimed method would only serve as the basis for further research on the observation itself. The claimed method itself and the proposed uses of the claimed method are simply starting points for further research and investigation into potential practical uses of the claimed methods. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." Brenner v. Manson, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101 because any potential utility of the claimed method is not yet known. Given these considerations, the claimed method has no "well-established" use. The artisan is

required to perform further experimentation to determine to what "use" any information regarding the results of the screening could be put. One must know the biological significance of such phosphorylation in order to determine what "use" the claimed method could be put. Without knowledge of this biological significance the results of the claimed method are useless because one would not know what significance could be attributed to any modulation in such phosphorylation.

Applicant argues that phosphorylation of the cell-bound TNF constitutes part of the normal way of TNF modulation, citing page 12, lines 17-20, of the specification. Applicants' arguments have been fully considered but they are not persuasive. An assertion that phosphorylation of the cell-bound TNF constitutes part of the normal way of TNF modulation is not specific because it does not indicate a modulation of a particular activity. Such an assertion is also not substantial because it does not indicate a particular way in which a particular activity is modulated.

Applicant argues that phosphorylation plays an important role in TNF function, citing page 13, lines 5-6, of the specification. Applicants' arguments have been fully considered but they are not persuasive. An assertion that phosphorylation plays an important role in TNF function is not specific and substantial because it does not indicate a particular role in a particular TNF function.

Applicant argues that the finding of phosphorylation of the intracellular domain of TNF provides a basis for pinpointing agents that can modulate the shedding of TNF or modulate the activity of TNF, citing page 14, lines 1-7, of the specification. Applicants' arguments have been fully considered but they are not persuasive. Based on the specification's disclosure at page 6, lines 3-10, (the "findings and their related functional

significance represent the first disclosure of a control possibility"), at the paragraph bridging pages 5-6 (the sequence conservation of the intracellular domain of TNF indicates that this domain and its phosphorylation play important roles in TNF function. One possibility is that this domain take part in the regulation of proteolytic processing. Another possibility is that this domain may affect TNF function as a ligand. Yet another possibility is that this intracellular domain interacts with other intracellular molecules.), and the disclosure at page 6, full paragraph 1, (the phosphorylation of the intracellular domain of TNF may be involved in the regulation of expression or proteolytic processing of cell-surface TNF, in the modulation of TNF bioactivity, or in the intracellular processes mediated by the cell surface TNF molecules), the disclosure at page 14, lines 1-7, of the specification is describing a "wish to know" type of utility, which is not a specific and substantial utility.

Applicant argues that compounds that modulate phosphorylation can be further tested for their biological activity, citing page 38 of the specification, and that this further screening in vivo for biological activity is a specific and substantial utility. Applicants' arguments have been fully considered but they are not persuasive. Firstly, page 38 discloses further testing of compounds that bind the intracellular domain of TNF and says nothing regarding the further screening of compounds that modulate phosphorylation. Secondly, this further testing of any compound that modulates phosphorylation would only serve as the basis for further research on the result of the claimed method itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." Brenner, 148 USPQ at 696. The

disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Applicant argues that the screening process is useful to find molecules that cause modulation of phosphorylation in view of the further assertion that such modulation would be expected to modulate the biological activity of TNF. Applicants' arguments have been fully considered but they are not persuasive. The statement that such modulation would be expected to modulate the biological activity of TNF is not specific because it does not indicate a modulation of a particular activity. Such a statement is also not substantial because it does not indicate a particular way in which a particular activity is modulated.

Applicant argues that compounds that modulate TNF may be used for the treatment of specific conditions, citing page 2, lines 8-29, of the specification. Applicants' arguments have been fully considered but they are not persuasive. Although compounds that modulate TNF activity may be used for the treatment of specific conditions, the biological significance of the phosphorylation of the intracellular domain of TNF is unknown. Consequently, it is unknown whether any such compounds found through the claimed method could be used for treatment of specific conditions.

Applicant argues that there is a specific assertion that that compounds found will have a specific and substantial use in treating specific conditions. Applicant's arguments have been fully considered but they are not persuasive. The biological significance of the phosphorylation of the intracellular domain of TNF is unknown. The specification lacks specific and substantial disclosure of a specific and substantial functional consequence of this phosphorylation. Thus the asserted utility in screening for factors that modulate the

phosphorylation of the intracellular domain of TNF is not substantial, because further research would have to be conducted to determine which, if any, of TNF activity or processing are modulated and how they are modulated. The claimed method itself and the proposed uses of the claimed method are simply starting points for further research and investigation into potential practical uses of the claimed methods. In the absence of a particular disclosed relationship between the phosphorylation of the intracellular domain of TNF and a particular functional consequence, any information obtained from the claimed method would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." Brenner v. Manson, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101. Because any potential utility of the claimed method is not yet known, any utility of the compounds found using the claimed screening process are not currently available in practical form.

Applicant argues that the successful screening test of the presently claimed invention will marshal resources and direct the expenditure of effort to further in vivo testing of the most potent compounds, which has been held to be a specific and substantial utility. Applicants' arguments have been fully considered but they are not persuasive. The biological significance of the phosphorylation of the intracellular domain of TNF is unknown. The specification lacks specific and substantial disclosure of a specific and substantial functional consequence of this phosphorylation. Thus the asserted utility in screening for factors that modulate the phosphorylation of the intracellular domain of TNF is not substantial, because further research would have to be

conducted to determine which, if any, of TNF activity or processing are modulated and how they are modulated. The claimed method itself and the proposed uses of the claimed method are simply starting points for further research and investigation into potential practical uses of the claimed methods. n the absence of a particular disclosed relationship between the phosphorylation of the intracellular domain of TNF and a particular functional consequence, any information obtained from the claimed method would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." Brenner v. Manson, 148 USPQ at 696. Because any potential utility of the claimed method is not yet known, any marshaling of resources and directing the expenditure of effort to further in vivo testing of the most potent compounds would only serve as the basis for further research on the observation itself. Because the claimed method itself and the proposed uses of the claimed method are simply starting points for further research and investigation into potential practical uses of the claimed methods any marshaling of resources and directing the expenditure of effort to further in vivo testing of the most potent compounds cannot be held to be a specific and substantial utility.

Applicant argues that the rejection under 35 U.S.C. § 112, first paragraph is based on the same reasons as the rejection under 35 U.S.C. 101 and should therefore be overturned. As Applicants recognize, a rejection under § 112, first paragraph, may be maintained on the same basis as a lack of utility rejection under § 101. A deficiency under 35 U.S.C. 101 also creates a deficiency under 35 U.S.C. 112, first paragraph. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also

fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112. Obviously, if a claimed invention does not have utility, the specification cannot enable one to use it. As such, a rejection properly imposed under 35 U.S.C. 101 should be accompanied with a rejection under 35 U.S.C. 112, first paragraph. The 35 U.S.C. 112, first paragraph, rejection set out a separate rejection that incorporates by reference the factual basis and conclusions set forth in the 35 U.S.C. 101 rejection. A 35 U.S.C. 112, first paragraph, rejection should be imposed or maintained when an appropriate basis exists for imposing a rejection under 35 U.S.C. 101.

Claims 29 and 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to "producing" a molecule. However, the specification does not describe the production of any and all molecules with the desired characteristics. At best it might be obvious to the skilled artisan that it would be desirable to employ the materials and methods disclosed in attempt to produce such molecules. However, the written description does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious.

Applicant argues that the claims do not require that any molecule which causes modulation of the phosphorylation be actually identified, and that in this regard the preset

case is similar to the Board decision in U.S. application serial no. 08054970, and that the same logic in the Board decision obviously applies to whether applicant was in possession of the method. Applicants' arguments have been fully considered but they are not persuasive. Applicant is reminded that Vas-Cath Inc. v. Mahurkar , 19 USPQ2d 1111 makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115). Accordingly, the same logic in the Board decision would not necessarily apply to whether applicant was in possession of the claimed method. It is true that a molecule that is not identified by the process need not be produced. However, in the present case the claims require producing in substantially isolated and purified form any said molecule which is determined to cause said modulation. The specification does not describe the production of any and all molecules with the desired characteristics.

Applicant argues that if no molecule is determined to cause the modulation then nothing need be produced. Applicants' arguments have been fully considered but they are not persuasive. It is true that a molecule that is not identified by the process need not be produced. However, in the present case the claims require producing in substantially isolated and purified form any said molecule which is determined to cause said modulation. The specification does not describe the production of any and all molecules with the desired characteristics.

Applicant argues that if a molecule is identified by the screening step then producing it is a trivial matter, citing page 27, lines 5-11. Applicants' arguments have been fully considered but they are not persuasive. Page 27, lines 5-11, of the present specification apparently refers to the screening of molecules that bind the intracellular

domain of TNF, whereas the present claims are directed to the screening of molecules that modulate the phosphorylation of the intracellular domain of TNF. As provided for in the present specification, molecules that modulate the phosphorylation of the intracellular domain of TNF are not limited to molecules that bind the intracellular domain of TNF and include molecules that interact with one or more other intracellular effector proteins which interact with the intracellular domain of TNF or with one or more kinase enzymes involved in the phosphorylation of the intracellular domain of TNF. See the present specification at page 6, full paragraph 3, and paragraph bridging pages 6-7. Accordingly, the claims are not limited to screening for molecules that bind the intracellular domain of TNF. Page 27, lines 5-11, of the present specification also provides for new proteins and peptides of the invention once isolated, identified, and characterized to be produced by any standard recombinant DNA technique. However, the present claims are not limited to the screening of peptides and proteins and are not limited to the production of peptides and proteins by any standard recombinant DNA technique. The present claims encompass the screening and production of any all molecules that modulate the phosphorylation of the intracellular domain of TNF. As provided for in the present specification, molecules that modulate the phosphorylation of the intracellular domain of TNF can be naturally-derived proteins, peptides, analogs and derivatives thereof, and organic compounds. Any standard recombinant DNA technique does not describe the production of any or all organic compounds capable of such modulation. Whether or not the production of any or all organic compounds capable of such modulation is trivial is dependent upon the compound.

Applicant argues that Applicant was in possession of the concept of producing a pure compound which has been identified, using synthesis processes already established in the art. Applicant's arguments have been fully considered but they are not persuasive. Production in substantially isolated and purified form any molecule which is determined to cause modulation of the phosphorylation of the intracellular domain of TNF is necessary to practice the claimed method. This production is only described in terms of a general concept and the specification does not describe the production of any and all molecules with the desired characteristics. Specific, not general, i.e., "producing", guidance is needed to practice the invention. The concept of producing the desired molecules is no more than a wish for obtaining the required producing process. The concept of producing the desired molecules contains no information by which the skilled artisan would understand that Applicant possessed the claimed invention. Without a specific producing process it is impossible to practice the claimed method. The present specification describes how to screen compounds to determine whether they work, but it does not describe the production of any and all molecules with the desired characteristics.

Applicant argues that Applicant is not claiming molecules, that Applicant is claiming a screen, and that Applicant is in possession of the concept of screening. Applicants' arguments have been fully considered but they are not persuasive. Production in substantially isolated and purified form any molecule which is determined to cause modulation of the phosphorylation of the intracellular domain of TNF is necessary to practice the claimed method. This production is only described in terms of a general concept and the specification does not describe the production of any and all molecules with the desired characteristics. Specific, not general, i.e., "producing",

guidance is needed to practice the invention. The concept of producing the desired molecules is no more than a wish for obtaining the required producing process.

Applicant argues that because the claim does not require that any such molecules be found it is not necessary to identify any such molecule, but that once identified the molecule can be produced, and therefore Applicant was in possession of the idea of producing any molecule found. Applicants' arguments have been fully considered but they are not persuasive. Production in substantially isolated and purified form any molecule which is determined to cause modulation of the phosphorylation of the intracellular domain of TNF is necessary to practice the claimed method. This production is only described in terms of a general concept and the specification does not describe the production of any and all molecules with the desired characteristics. Specific, not general, i.e., "producing", guidance is needed to practice the invention. The concept of producing the desired molecules is no more than a wish for obtaining the required producing process.

Applicant argues that there is nothing in 35 U.S.C. § 112, first paragraph which requires that such molecules be identified before one can be in possession of a screening process. Production in substantially isolated and purified form any molecule which is determined to cause modulation of the phosphorylation of the intracellular domain of TNF is necessary to practice the claimed method. This production is only described in terms of a general concept and the specification does not describe the production of any and all molecules with the desired characteristics. Specific, not general, i.e., "producing", guidance is needed to practice the invention. The concept of producing the desired molecules is no more than a wish for obtaining the required producing process.

Claims 29, 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to "producing" a molecule. However, the specification does not describe the production of any and all molecules with the desired characteristics. In the absence of this information the skilled artisan would have to resort to a substantial amount of unduly extensive, random, trial and error experimentation in the form of random analysis of any and all compositions and/or compounds and through trial and error experimentation is left to determine how to isolate and produce them. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Applicant refers to the Board decision in U.S. application serial no. 08/054,970 and Applicant's reconstruction of the passage at page 8 of the decision is acknowledged. Applicants' arguments have been fully considered but they are not persuasive. It is not a question of whether the screening step would or would not determine if a molecule causes modulation of the phosphorylation. It is a question of whether the specification has enabled the production in substantially isolated and purified form any such molecule which is determined to cause such modulation.

Applicant argues that the production in substantially isolated and purified form any such molecule which is determined to cause such modulation would not require undue experimentation because the specification teaches how to run a screen, citing example 6 of the present specification. Applicants' arguments have been fully considered but they are not persuasive. Example 6 of the present specification essentially calls for the use of trial and error experimentation to attempt to find a compound that may in some way be related to phosphorylation of the intracellular domain of TNF. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute an enabling disclosure. Reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. However, the present specification does not describe a repeatable process of producing any and all molecules with the desired characteristics. When there is no disclosure of the conditions under which the required producing process can be carried out, undue experimentation is required. There is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. The specification does not explain how the skilled artisan can produce in substantially isolated purified form any or all molecules that modulate phosphorylation of the intracellular domain of TNF.

Applicant argues that running a screen is not random trial and error. Applicants' arguments have been fully considered but they are not persuasive. The mere running of a screen is nothing but random, trial and error experimentation.

Applicant argues that the present claims are directed to a screening process and not to the molecules found. Applicants' arguments have been fully considered but they are not persuasive. The claims require producing in substantially isolated and purified form any said molecule which is determined to cause said modulation. It is this "producing" process that is the subject of this rejection.

Applicant argues that "a substantial amount of unduly extensive, random, trial and error experimentation in the form of random analysis of any and all compositions and/or compounds and through trial and error experimentation" is merely conclusionary, without analytic back-up, and is no substitute for a fact-based explanation why undue experimentation is required. Applicants' arguments have been fully considered but they are not persuasive. The specification does not describe the production of any and all molecules with the desired characteristics. In the absence of this information the skilled artisan would have to resort to a substantial amount of unduly extensive, random, trial and error experimentation in the form of random analysis of any and all compositions and/or compounds and through trial and error experimentation is left to determine how to isolate and produce them. The rejection is based on no disclosure of the conditions under which the required producing process can be carried out. When there is no disclosure of the conditions under which the required producing process can be carried out, undue experimentation is required. There is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. The specification does not explain how the skilled artisan can produce in substantially isolated purified form any or all molecules that modulate phosphorylation of the intracellular domain of TNF.

Conclusion

No claims are allowable.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
NOVEMBER 18, 2003